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EXAMINER	
PATTERSON, MARC A	

ART UNIT	PAPER NUMBER
1772	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/733,079	Applicant(s) ANDERSSON ET AL.	
	Examiner Marc A Patterson	Art Unit 1772	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase 'consists of up to 60 to 100% by weight of polypropylene materials and up to 40 to 0% by weight of a thermoplastic elastomer' is indefinite, because 'consisting of' language is used but the phrase 'up to' makes it unclear whether the composition percentages add up to 100%. For purposes of examination, the phrase 'consisting of' will be assumed to mean 'comprising.' The phrase 'wherein following hot steam sterilization at 121 degrees Celsius the film displays no measurable yield according to DIN EN ISO 527-1' is indefinite as the term DIN EN ISO 527-1 is a standard, which may change with time. The standard is also not defined in the claim, thus the term 'yield' has not been defined. The phrase also is directed to a process, which is given little patentable weight as discussed below. The term "hot" in claim 1 is a relative term which renders the claim indefinite. The term "hot" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to Claim 14, the phrase 'the middle layer has a measurable yield' is indefinite, as the measurement, and therefore the term 'yield,' have not been defined. The phrase 'when measured separately' is indefinite as its meaning is unclear. The phrase also appears to be directed to a process, which is given little patentable weight.

4. Claims 10 – 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms 'MPa' and 'Mpa' are indefinite as the abbreviations have not been defined. For purposes of examination, the abbreviations will be assumed to mean 'megapascals.'

5. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases 'consist of up to' and 'consist additionally of up to' are indefinite because 'consisting of' language is used but the phrase 'up to' makes it unclear whether the composition percentages add up to 100%. For purposes of examination, the phrase 'consisting of' will be assumed to mean 'comprising.'

6. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase 'consist additionally of up to' is indefinite because 'consisting of' language is used but the phrase 'up to' makes it unclear whether the composition percentages add up to 100%. For purposes of examination, the phrase 'consisting of' will be assumed to mean 'comprising.'

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 – 7, 14 and 20 – 33, are rejected under 35 U.S.C. 102(b) as being anticipated by Heilmann et al (U.S. Patent No. 5,783,269).

With regard to Claims 1, 14 and 23, Heilmann et al disclose a multi – layer film comprising three layers; an inner (supporting), outer and middle layer (column 3, lines 43 – 54); each layer comprises 100% polypropylene homopolymer (column 5, lines 23 – 59); with regard to the claimed aspect of the film 'displaying no measurable yield following steam sterilization at 121 degrees Celsius using a water spraying process,' the scope of the claims falls within the limitations of Heilmann et al as discussed above. The method of obtaining the yield (product – by – process) is given little patentable weight.

With regard to Claims 2 – 4, the proportion of the thickness represented by the middle layer is 70% (column 4, lines 8 – 17).

With regard to Claims 5 – 6, the proportion of the thickness represented by the outer layer is 15% (column 4, lines 8 – 17).

With regard to Claim 7, the total thickness of the film is 130 μm (column 4, lines 8 – 17).

With regard to Claim 24, the inner layer consists of 90% polypropylene homopolymer and 10% polypropylene copolymer (column 5, lines 45 – 50).

With regard to Claim 25, the Heilmann et al teach addition of styrene – ethylene / butylene – styrene block copolymers to the layers of polypropylene (column 9, lines 31 – 37); the claimed aspect of the outer layer 'comprising styrene – ethylene / butylene – styrene block copolymers' therefore reads on Heilmann et al.

With regard to Claims 26 – 27, Heilmann et al teach that five and seven layered films are equivalent to three layered films (column 4, lines 18 – 25). The claimed aspect of the film having five or seven layers having the sequence (A-M-A-M-I) or (A-M-A-M-A-M-I) therefore reads on Heilmann et al.

With regard to Claims 28 – 31, the scope of the claims falls within the limitations of Heilmann et al as discussed above. The method of making the film (product – by – process) is given little patentable weight. Applicant would need to demonstrate, by verified showing, the unexpected advantages accruing from the methods of making as claimed.

With regard to Claim 32, Heilmann et al disclose a packaging comprising a multi – layer film (a bag; column 1, lines 16 – 20).

With regard to Claim 33, the packaging stores parenteral fluids (which are water – based; column 7, lines 64 – 67).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8 – 9 and 18 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269).

Heilmann et al disclose a film having an outer layer, and inner layer and a middle layer as discussed above. With regard to Claims 8 – 9 and 18 – 19, Heilmann et al fail to disclose a total film thickness of 150 – 250 μm, and a melting point of the inner layer which is less than that of the outer layer, and the melting point of the middle layer is less than that of the outer layer and greater than that of the inner layer. However, Heilmann et al disclose a film thickness of 130 μm, as discussed above, and a melting point of the inner layer which is the same as that of the outer layer, (column 7, lines 39 – 47), and a melting point of the middle layer which is less than the outer layer (column 3, lines 20 – 30). Therefore, the range of thickness and melting point of the middle layer and melting point of the inner layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the range of thickness and melting point of the middle layer and melting point of the inner layer, since the

range of thickness and melting point of the middle layer and melting point of the inner layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al. *In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980).*

11. Claims 20 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269).

Heilmann et al disclose a film having an outer layer, and inner layer and a middle layer as discussed above. With regard to Claims 20 – 22, Heilmann et al fail to disclose a middle layer having a Vicat temperature of 40 – 65 degrees Celsius, and an outer and inner layer having Vicat temperatures less than or equal to 121 degrees Celsius. However, Heilmann et al disclose a middle layer having a Vicat temperature of 40 – 65 degrees Celsius (less than 70 degrees Celsius; column 2, lines 41 – 59), and an outer and inner layer having Vicat temperatures above 121 degrees Celsius (column 2, lines 42 – 59). Therefore, the Vicat temperatures of the inner and outer layers would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the Vicat temperatures of the inner and outer layers, since the Vicat temperatures of the inner and outer layers would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al. *In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980).*

12. Claims 10 – 13 and 15 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Laurin et al (U.S. Patent No. 5,686,527).

Heilmann et al disclose a multi – layer film which is sterilizable, as discussed above. With regard to Claims 10 – 13 and 15 – 17, Heilmann et al fail to disclose a film in which the elasticity modulus of the middle layer is less than 100 MPa, and a film in which the elasticity modulus of the outer layer is greater than 400 MPa.

Laurin et al teach a modulus of elasticity for a sterilizable film, ranging from 22 – 45 kilopounds per square inch (150 – 300 MPa; column 10, lines 1 – 30) for the purpose of making a film which is easy to manufacture into useful articles (column 1, lines 45 – 54).
It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a modulus of elasticity for a sterilizable film, ranging from 22 – 45 kilopounds per square inch in Heilmann et al in order to make a film which is easy to manufacture into useful articles as taught by Laurin et al.

Laurin et al fail to disclose a modulus of elasticity of greater than 400 MPa. However, Laurin et al. disclose a modulus of elasticity of 150 – 300 MPa. Therefore, the modulus of elasticity would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the modulus of elasticity, since the modulus of elasticity would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Laurin et al. *In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980).*

13. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Barney et al (U.S Patent No. 6,348,568).

Heilmann et al disclose a packaging which stores parenteral fluids as discussed above. Heilmann et al fail to disclose a packaging which stores fluid lipophilic emulsions.

Barney et al teaches that parenteral fluids and lipophilic emulsions are equivalent as aqueous solutions (column 58, lines 63 – 67; column 59, lines 1 – 10) for the purpose of preparing an oily injection mixture (column 58, lines 63 – 67).

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for storage of lipophilic emulsions in Heilmann et al in order to prepare an oily injection mixture as taught by Barney et al.

ANSWERS TO APPLICANT'S ARGUMENTS

14. Applicant's arguments regarding the 35 U.S.C. 112 second paragraph rejection of Claims 1 – 34, 35 U.S.C. 102(b) rejection of Claims 1 – 7, 14 and 20 – 33 as being anticipated by Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 8 – 9 and 18 – 19 as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 20 – 22 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Laurin et al (U.S. Patent No. 5,686,527), 35 U.S.C. 103(a) of Claim 34 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Barney et al (U.S Patent No. 6,348,568), of record on page 2 of the

previous Action, have been considered and have been found to be persuasive. The rejections are therefore withdrawn. The new 35 U.S.C. 112 second paragraph rejection of Claims 1 – 34, 35 U.S.C. 102(b) rejection of Claims 1 – 7, 14 and 20 – 33 as being anticipated by Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 8 – 9 and 18 – 19 as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 20 – 22 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269), 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Laurin et al (U.S. Patent No. 5,686,527), 35 U.S.C. 103(a) of Claim 34 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Barney et al (U.S Patent No. 6,348,568) above are directed to amended Claims 1 – 34.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Patterson, whose telephone number is (703) 305-3537. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by phone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (703) 308-4251. FAX communications should be sent to (703) 872-9310. FAXs received after 4 P.M. will not be processed until the following business day.

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HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

1/23/03